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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,420	08/26/2005	Richard O Chen	27763-705.831	5778

21971 7590 05/20/2009

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EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
05/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,420	CHEN ET AL.	
	Examiner	Art Unit	
	LORI A. CLOW	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 45-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/10/2005;12/7/2007;3/20/2009;5/7/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 26-44 in the reply filed on 18 February 2009 is acknowledged.

Claims 1-25 and 45-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 February 2009.

Claims 26-44 are examined herein.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be

submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Because priority is not properly claimed in the instant application, for purposes of applying prior art, the effective filing date accorded herein is the filing date of the PCT application which is 3 February 2003.

Information Disclosure Statement

The Information Disclosure Statements filed 10 June 2005, 7 December 2007, 20 March 2009, and 7 May 2009 have been considered. Signed copies of PTO forms 1449 are included with this Office Action.

Drawings

The drawings submitted 23 July 2004 are accepted.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Please see page 26, line 29. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101-Non-statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 26-44 are drawn to a method for evaluating user-supplied genomics data using a structured database that permits the computation of complex relationships among genes and/or gene products contained in the database comprising defining profiles, building a collection of profiles, identifying overlapping profiles and analyzing statistically significant profiles.

As stated in MPEP 2106, section IV if the claims are found to cover a judicial exception then the claims will be evaluated for providing a practical application of the judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). This is in line with the recent decision in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

As such, the claims must be further evaluated for providing the practical application. One way to do this is for the claim to produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e.

reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case the steps of "displaying " **does** provide a tangible result that is useful to one skilled in the art and thus provides a practical application for claims 39 and 41. However, claims 26-38, 40, and 42-44 provide no such practical application.

In addition to the facts set forth above that state that a claim must provide a practical application, the claim **must also meet** the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept **may have a practical application,** a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, the method claims are not so tied to another statutory class of invention because the method steps that are critical to the invention are "not tied to any **particular apparatus** or **machine**" and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites "the method of claim 26, wherein the generating a profile library step includes…". There is insufficient antecedent basis in the claim for "generating a profile library" as no such step is present in claim 26. Correction is requested.

Claim 44 recites, "the method of claim 26 wherein the generating step includes…". There is insufficient antecedent basis in the claim for "the generating step", as no such step occurs in claim 26. Correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-41 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by 2004/0249620 (Chandra et al.; effective filing date of 20 November 2002).

The instant claims are drawn to a method for evaluating user-supplied genomics data using a structured database that permits the computation of complex relationships among genes and/or gene products contained in the database comprising defining profiles, building a collection of profiles, identifying overlapping profiles and analyzing statistically significant profiles.

Chandra et al. teach an epistemic engine system and method for accepting biological data from experiments or other sources to produce a model, such as a genomic or protein interaction network.

In regard to claim 26, Chandra teaches defining a profile model, such as representations of functions of a pair of molecules (paragraphs 0009; 0016; 0030). Chandra further teaches building a collection of profiles such as selecting objects within a representation structure and specifying descriptors between selected pairs or groups of at least portions of objects to produce a network, web, matrix, or other form of electronic model (paragraphs 0010; 0054). Chandra teaches identifying profiles that overlap and assessing them statistically such as comparing simulated data to experimentally derived data and computing behaviors or properties of the hypothetical system to determine the degree of consistency with observed or hypothesized data. The system may be scored (paragraph 0010; paragraph 0013).

In regard to claims 27 and 44, Chandra teaches models that include established nodes and descriptors from knowledge that is already known to exist in literature and from already performed experiments (paragraph 0011; 0031).

In regard to claim 28, Chandra teaches establishing directed graphs which may be further used to represent relationships and further represented by matrices, vectors, multi-dimensional arrays or other structured representations (paragraph 0040).

In regard to claim 29, Chandra teaches querying knowledge stored in a knowledge base (paragraph 0031).

In regard to claim 30, Chandra teaches statistical analysis of comparisons of relationship data (paragraph 0013).

In regard to claim 31, Chandra teaches that genomic information may be gene product information or gene information or biological process information (paragraphs 0019 and 0020).

In regard to claim 32, Chandra teaches differential gene expression data and analysis to identify uses for drugs in clinical trials paragraph 0017).

In regard to claim 33, Chandra teaches gene expression data related to disease may be analyzed, in which models of biomarkers may be generated (paragraph 0020).

In regard to claim 34, Chandra teaches profile criterion generated from biological processes, for example (paragraph 0019).

In regard to claims 35 and 36, Chandra teaches seed node generation and nodes representing genes or gene products or biological processes (paragraphs 0009; 0011; 0017; 0036).

In regard to claim 37, Chandra teaches computing scores using statistical correlation for comparing steps (paragraph 0013).

In regard to claim 38, Chandra teaches nodes linked to neighboring nodes (paragraphs 0009 and 0011).

In regard to claims 39 and 41, Chandra teaches the display of information as the techniques are computer performed and the display is in the form of a graphical user interface, as shown in Figures 1 and 3.

In regard to claim 40, Chandra teaches annotating profiles with disease process information (Figure 3=literature based findings/other findings; paragraphs 0011; 0048).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26, 40, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over 2004/0249620 (Chandra et al.; effective filing date of 20 November 2002), as applied to claims 26 and 40 above, in view of Qu et al. (Intelligent Systems in Biology (2002) March/April, pages 21-27; PTO Form 1449 reference).

In regard to claim 26, Chandra teaches defining a profile model, such as representations of functions of a pair of molecules (paragraphs 0009; 0016; 0030). Chandra further teaches building a collection of profiles such as selecting objects within a representation structure and specifying descriptors between selected pairs or groups of at least portions of objects to produce a network, web, matrix, or other form of electronic model (paragraphs 0010; 0054). Chandra teaches identifying profiles that overlap and assessing them statistically such as comparing simulated data to experimentally derived data and computing behaviors or properties of the hypothetical system to determine the degree of consistency with observed or hypothesized data. The system may be scored (paragraph 0010; paragraph 0013).

In regard to claim 40, Chandra teaches annotating profiles with disease process information (Figure 3=literature based findings/other findings; paragraphs 0011; 0048).

Chandra does not specifically teach annotations found in ontology nor does Chandra specifically teach the kind of statistical significance testing used that includes null hypothesis over probability. However, Qu et al. teach a system and method for integrating multidimensional data for relationship inference in genomics systems by implementing data from gene ontologies (page 22, column 3). Qu et al. also teach the calculation of relationship

inference by statistical methods such as cluster analysis using hierarchical clustering employing the Pearson correlation coefficient to construct a relationship tree (page 24, column 3), showing that, in addition to the algorithms used by Chandra, various other statistical methodology may be employed to analyze relationship data for overlapping pathways, therefore making it prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the well-know statistical method of null hypothesis and probability distribution to analyze statistical significance of pathway overlap. Further, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have gained ontology data, such as that gained in Qu et al. in the system of Chandra. One would have had a reasonable expectation of success in doing so because such databases were known and developed at the time of the invention and readily available for scientific use. Chandra teaches gaining information from a myriad of sources, including literature based findings and other findings (Figure 3).

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

May 20, 2009
/Lori A. Clow, Ph.D./
Primary Patent Examiner
Art Unit 1631